

### REMARKS

Claims 1-5, 7-12, 14, 16, 18 and 22-25 are currently pending in the application. Claims 1, 4, 8 and 12 are amended. That the barbs are formed on the long helical edge of a helically wrapped ribbon is found in the specification, drawings and claims as originally filed, such as in Figs. 4 and 5 and in the specification at page 2, lines 22-25, page 4, lines 3-9 and page 6, lines 16-29. No new matter is added.

### APPLICANT'S INVENTION

Applicant's invention concerns tissue implant devices that are configured to resist migration after implantation. One aspect of the invention comprises a flexible, helical coil, formed from a filament. The coiled filament has a helical edge and a plurality of barbs spaced along and projecting from the edge, the barbs being adapted to engage the tissue in which the device is implanted. Figs. 4 and 5, reproduced below, illustrate two embodiments. The filament can have a rectangular cross-section. The coil can be made from a plurality of materials, each having a different modulus of elasticity.

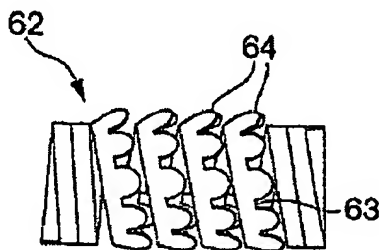


Fig. 4

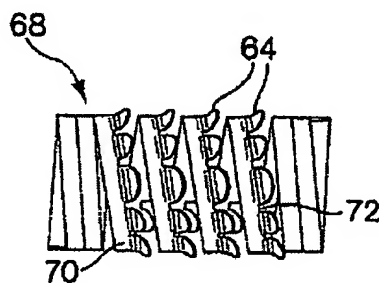


Fig. 5

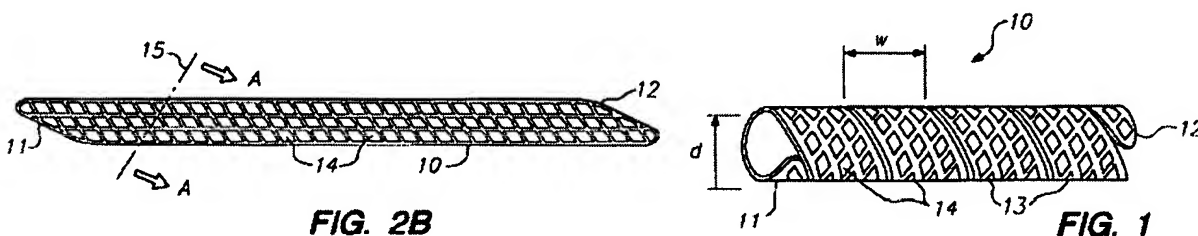
Another aspect of the invention relates to methods of forming such devices. The methods can include the steps of forming, from a sheet of material via a photochemical etching process, a ribbon-like filament having barbs on the edge of the ribbon, then separating the ribbon from the

sheet of material, and then wrapping the ribbon into a helical coil, and forming it so that the barbs project along the edge.

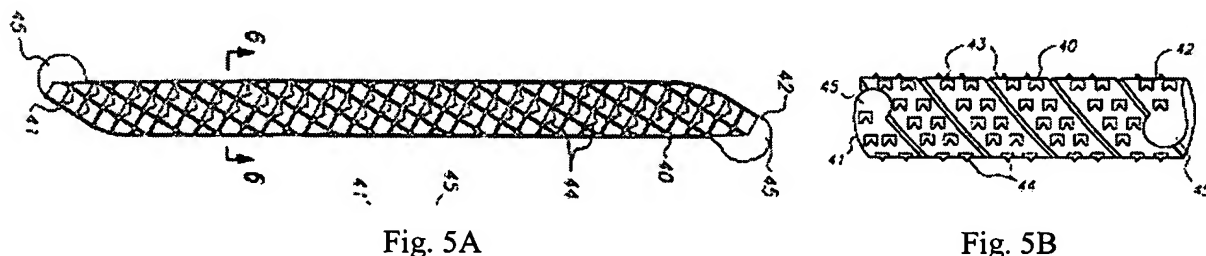
### CITED REFERENCES

#### Khosravi et al. (U.S. Pat. No. 5,824,053; "Khosravi")

Khosravi discloses a stent made from a perforated band (Fig. 2B of Khosravi, below) wound at an angle to produce a tubular structure (Fig. 1 of Khosravi, below). The perforations in the band define a multiplicity of openings which form a lattice providing about 60% open space or more (Abstract).

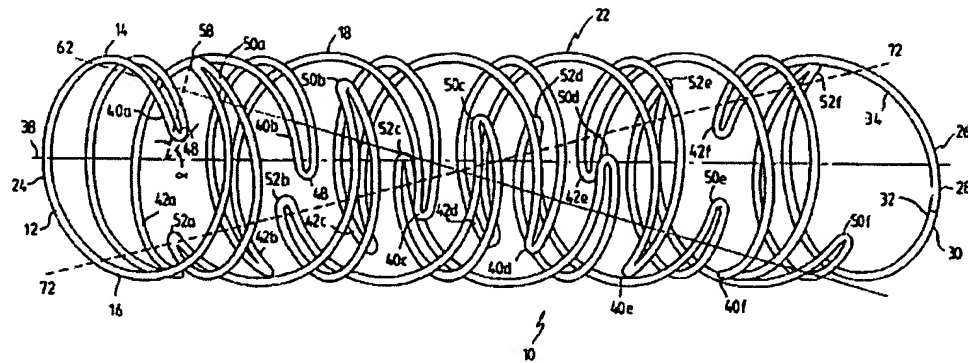


In embodiments shown in Figs. 5A and 5B (below) barbs are formed within the body of the band and project into the openings. When the band is rolled to form the tubular coil, the barbs project outwardly from the surface of the stent.



#### Summers (U.S. Pat. No. 5,607,445; "Summers")

Summers discloses a stent which includes a coil having a plurality of arcuate sections that alternate directions around a central axis. The stent can be made from a flat sheet of material which is photochemically etched to form a blank, and the blank is then formed into the coil.



**Ahern (U.S. Pat. No. 6,620,170; "Ahern")**

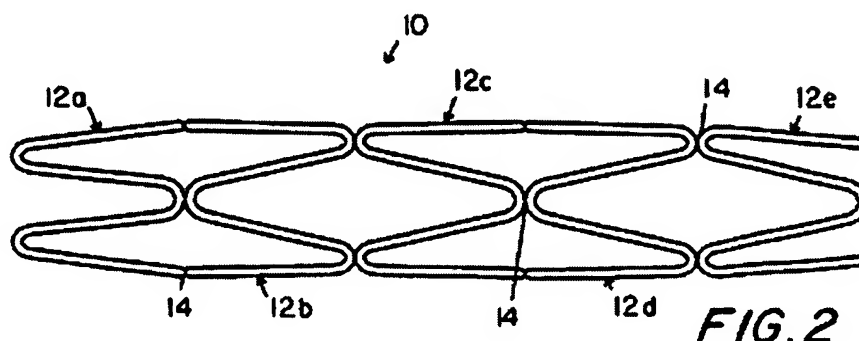
Ahern discloses devices and methods intended to induce fibrin growth in tissue and to promote revascularization of the tissue after implantation of the device. The device can be a frame configured to foster growth of fibrin and to permit communication between the fibrin and the surrounding tissue. The device can be associated with a fibrin promoting substance, or associated with formed fibrin. The device can also be associated with a formed thrombus or a thrombophilic substance. One of the devices is illustrated in Fig. 7, reproduced below, which is described (at column 6, lines 62-63) as a side view of an implant device comprising a canted coil, where the coils have smooth edges.



**Lashinski et al. (U.S. Pat. No. 5,868,780; "Lashinski")**

Lashinski discloses stents to hold open a tubular body structure or lumen. The stents have at least one axial portion that holds the lumen open with less force than other portions of the stent (column 3, lines 43-65). This "partial collapse" of the end(s) is intended to avoid abrupt

transitions between the stented and unstented regions of the lumen, which can trigger a reaction at or near the site of the transition (column 1, lines 27-34).



This “partial collapse” is shown in Fig. 2 (above), which shows the ends 12a and 12e slightly collapsed inwardly relative to the middle section 12c. One method of accomplishing this partial collapse is described at column 3, lines 50-54, which states that the end sections 12a and/or 12e can be made from a material having a lower modulus of elasticity or spring force than other sections.

### **CLAIM REJECTIONS**

#### **Claim Rejections Under 35 U.S.C. § 103**

Reconsideration is requested of the rejection of claims 1-5, 7 and 12 as defining subject matter that would have been obvious to one of ordinary skill in the art over Khosravi. Each of those claims includes limitations to placement of the barbs along the long edge of a helically wound coil. Where Khosravi does not disclose placement of the barbs along the long edge of the ribbon before it is wound, but instead places them internal to the ribbon, this ground of rejection cannot be sustained. In Khosravi, all of the long edges of the mesh are smooth, while the current claims all require barbs along the long edge of the ribbon. The claimed subject matter therefore cannot be obvious in view of this reference.

Reconsideration is also requested of the rejection of claims 14 and 16-18 as defining subject matter that would have been obvious to one of ordinary skill in the art over Khosravi and

Summers. As discussed above, Khosravi does not disclose placement of the barbs along the long edge of the ribbon, but instead places them internal to the ribbon. Summers likewise fails to disclose a tissue implant device as claimed. Where none of the references discloses the claimed placement of barbs along the long edge of a helically wound filament, their combination cannot render those claims obvious. The reference to Ahern in the rejection of claims 14 and 16-18 is not understood as being relevant to the rejection.

Claims 8-11 and 22 were also rejected in view of Ahern and Lashinski as defining subject matter that would have been obvious to one of ordinary skill in the art. However, the provisions of 35 U.S.C. §103(c) mandate that the Ahern reference is not prior art. At the time of filing of both the present application and the Ahern patent, the inventors of each were subject to an obligation to assign to C.R. Bard, Inc. at the time of filing. Copies of the assignment for the present application and the Ahern reference are filed herewith as Exhibits A and B. Additionally, it is not considered necessary for applicant to swear back of Ahern where published documents demonstrate, irrefutably, prior possession by applicant of the subject matter in Ahern on which the rejection is based (FIG. 7 of Ahern). That applicant was in possession of the subject matter of FIG. 7 of Ahern is the proper subject for official notice. See M.P.E.P. §2144.03. As acknowledged in the action, neither Ahern nor Lashinski discloses a tissue implant device formed from a filament with an edge along its length along which is formed a plurality of barbs that project from the edge and are adapted to engage surrounding tissue, where the filament is configured in a flexible helical coil having a plurality of turns. Claim 8 has been amended to reflect this limitation.

The rejection proceeds on the notion that “Ahern discloses the invention as claimed noting figure 7 comprising: A tissue implant made of a flexible helical coil having a plurality of *barbs projecting* from the edge.” (office action, pages 3-4). However, on page 8 of the action, it is agreed that Ahern does not disclose the claimed barbs. It is not clear, nor is it explained in the action, how the device as claimed and shown in Figs. 4 and 5 of the present application is obvious in view of Fig. 7 of Ahern where neither Ahern nor Lashinski disclose the barbs as claimed.

Fig. 7 of Ahern



Fig. 4 of present application

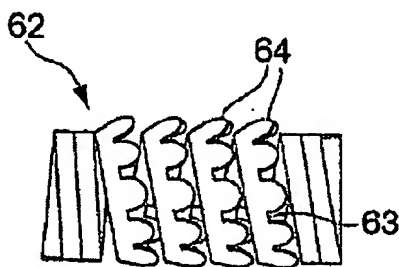
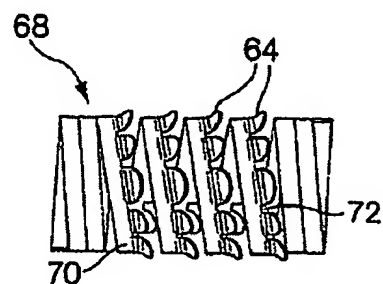


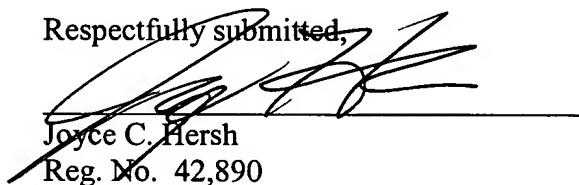
Fig. 5 of present application



The barbs formed along the long, helically-coiled edge in Figs. 4 and 5 are simply not present in Ahern. Lashinski likewise shows no such barbs. The rejection on the basis of these references must be withdrawn.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,



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